

## REMARKS

Claims 1-35, 43 and 45-55 are pending in the present application. By this Amendment, previously presented claims 1-2, 4, 6, 9-10, 12-16 and 43 have been amended, previously presented claims 36-42 and 44 have been canceled, and newly presented claims 48-55 have been added. Applicants respectfully request reconsideration of the present claims in view of the foregoing amendment and the following remarks.

### I. Formal Matters:

#### Allowable Subject Matter

Applicants note with appreciation that previously presented claims 4-5, 11-16, 20-22, 30-31, 33, 44 and 47 are objected to as being dependent upon a rejected base claim and would be allowable if rewritten in independent form. As shown above, previously presented (and objected to) claim 44 have been rewritten in independent form as newly presented independent claim 43.

For at least the reasons provided below, Applicants respectfully submit that all of claims 1-35, 43 and 45-55 are allowable over the art of record. Accordingly, allowance of all of claims 1-35, 43 and 45-55 is respectfully requested.

#### Objection to Specification

Applicants have reviewed the present application as filed and can not find any use of the term “calorimetric” in the original specification. Applicants are more than willing to change “calorimetric” to “colorimetric” throughout the original specification; however, it does not appear that any amendments to the original specification are necessary.

### II. Prior Art Rejections:

#### Rejection of Previously Presented Claims 1-3, 7-10, 17-19, 23-28, 32, 34, 41-42 and 45 Under 35 U.S.C. §103(a) In View of U.S. Patent No. 7,153,651 (Drewes) in view of U.S. Patent No. 5,869,272 (Bogart)

Previously presented claims 1-3, 7-10, 17-19, 23-28, 32, 34, 41-42 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable in view of U.S. Patent No. 7,153,651

issued to Drewes et al. (hereinafter, "Drewes") in combination with U.S. Patent No. 5,869,272 issued to Bogart et al. (hereinafter "Bogart"). This rejection is respectfully traversed.

The teaching of Drewes is directed to specific flow-through optical assay devices comprising (i) a support layer, (ii) an optically functional layer on the support layer, (iii) an optional anti-reflective layer on the optically functional layer, (iv) an attachment layer on the optically functional layer or the anti-reflective layer, and (v) an optional receptive material layer on the attachment layer. See, for example, FIG. 1 of Drewes.

Drewes discloses a number of materials for forming each of the above-referenced layers. For the optically functional layer, Drewes discloses a number of inorganic materials such as titanium and iron oxide in column 13, lines 35-48. For the optional anti-reflective layer, Drewes also discloses a number of inorganic materials such as aluminum oxide and diamond-like carbon in column 13, lines 53-62. For the attachment layer, Drewes discloses a number of materials including silanes, siloxanes, and polymers, as well as inorganic materials such as nickel and gold in column 15, lines 33-48. As disclosed in column 15, lines 6-10, the purpose of the attachment layer in Drewes is (1) to promote and enhance adhesion or attachment of the analyte specific binding reagent (i.e., the optional receptive material layer) to the optically functional layer or (2) provide a surface for non-specific capture of an analyte. It should be noted that Drewes specifically discloses in column 15, lines 33-34 that the attachment layer "must bind protein or undergo some thickness change itself upon analyte capture."

The teaching of Bogart is directed to specific analyte-detection devices having an optically active surface. Exposure of the optically active surface of the device to an analyte provides a visual color change. Referring to FIGS. 6A-6F, the disclosed devices of Bogart comprise (i) a base substrate layer (1), (ii) an optional metal film layer (6) on base substrate layer (1), (iii) an optional amorphous silicon layer (5) on base substrate layer (1) or metal film layer (6), (iv) an optional optical thin film (2) on base substrate layer (1) or amorphous silicon layer (5), (v) an attachment layer (3) on base substrate layer (1) or amorphous silicon layer (5) or optical thin film (2), and (vi) a receptive material layer (4) on attachment layer (3).

Regarding the rejection of Applicants' previously presented claims 1-3, 7-9 and 41-42, the September 24, 2007 Office Action states the following from page 3, line 14 to page 4, line 10:

Regarding claims 1-3, 7-9, 41, and 42 Drewes discloses a colorimetric sensor for measuring one or both of the presence and concentration of an analyte, said calorimetric sensor comprising: a substantially continuous reflective layer (the base layer of column 13, lines 16-29); a detection layer over the reflective layer (the AR layer of column 13, lines 53-62), said detection layer being capable of a change in optical thickness upon exposure to said analyte (column 14, lines 39-47); and a semi-reflective layer over the detection layer, the semi-reflective layer having an index of refraction different from the index of refraction of the detection layer (see attachment layer of column 15, lines 42-67), wherein at least a portion of the semi-reflective layer is permeable to said analyte (see claim 1). Examiner makes an argument of inherency for reflective, semi-reflective, and refractive index properties for the different embodiments of reference invention. Drewes does not disclose the material of the detection layer to be a polymer, however.

Bogart discloses an attachment layer being capable of change in optical thickness consisting of polymers (column 4 lines 1-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymer for the detection layer since many different polymers are known to perform the same function as the metals Drewes uses. The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicants agree that the teaching of Drewes fails to disclose, teach or suggest the use of a polymeric material in the optically functional layer(s) of Drewes' devices; however, Applicants disagree that one skilled in the art would have substituting the polymeric attachment layer in the devices of Bogart for an optically functional layer in the devices of Drewes.

Applicants respectfully submit that there is no suggestion or motivation in the teaching of Drewes alone, or in combination with the teaching of Bogart, that would have lead one skilled in the art to incorporate the polymeric attachment layer of Bogart into the devices of Drewes as an anti-reflective layer or any other optically functional layer in the devices of Drewes. Applicants could possibly envision one skilled in the art substituting the polymeric attachment layer of Bogart for the attachment layer in the devices of Drewes; however, there simply is no

suggestion to one skilled in the art to (1) remove the polymeric attachment layer from Bogart's devices, and (2) substitute the polymeric attachment layer from Bogart's device for the anti-reflective layer or other optically functional layer in the devices of Drewes.

As noted above, the September 24, 2007 Office Action states:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a polymer for the detection layer since many different polymers are known to perform the same function as the metals Drewes uses. The claim would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicants respectfully submit that the teaching of Drewes alone, or in combination with the teaching of Bogart, does not disclose, teach or suggest that the polymeric attachment layer materials disclosed in Bogart "perform the same function" as the optically functional layer materials disclosed in Drewes as suggested in the September 24, 2007 Office Action. Bogart specifically discloses that the polymeric attachment layer materials are present to "create a favorable environment for the receptive material, permit the receptive material to be bound in active, functional levels (preferably by a cost-effective method), adhere tightly to the optical substrate, and be coated uniformly" (see, Bogart, column 25, lines 12-35). In contrast, Drewes specifically discloses that the optically functional layer(s) materials are designed to "modify the optical properties of the support material so that the desired degree of reflectivity, transmittance, and/or absorbance is suited to the final assay configuration" and/or "attenuate one or more, or a range of wavelengths of light so that a result is observable visually or by instrumented analysis in the final device upon analyte binding" or "modify the optical parameters of the device to allow a change in the state or degree of polarization in the incident light" (see, Drewes, column 4, line 60 to column 5, line 11).

It is difficult for Applicants to understand why one skilled in the art would have been motivated to make the above substitution as suggested in the September 24, 2007 Office Action given that in both the Drewes' devices and the Bogart devices, the disclosed attachment layers, whether inorganic or polymeric, function to bind a receptive material (i.e., a material reactive to a given analyte) to the device and/or bind an analyte to the device, not to provide

optically functionality to the disclosed devices. Applicants respectfully submit that the only motivation for the proposed substitution of the polymeric attachment layer from Bogart's device for an optically functional layer in the devices of Drewes has been gleaned from Applicants' claimed invention, not from the art of record. For at least this reason, Applicants respectfully submit that the proposed combination of the teaching of Drewes with the teaching of Bogart, and the subsequent modification of the devices of Drewes in improper.

Regarding independent claim 45, the September 24, 2007 Office Action further states the following from page 5, line 20 to page 6, line 6:

Regarding claim 45, Drewes disclose the use of an inorganic detection layer (the AR layer of column 13, lines 53-62) and Bogart discloses the use of multiple polymers in the detection layer (column 4, lines 1-3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include some combination of these layers for the various analytes the materials would be appropriate for testing. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Applicants disagree.

As noted above, Bogart does not disclose, teach or suggest the use of polymers in a detection layer as suggested by the Office Action. Bogart discloses the use of various polymeric materials as an attachment layer suitable for binding an analyte receptive material to the disclosed devices, but does not disclose, teach or suggest the use of polymers in a detection layer.

In addition, it should be noted that the proposed combination of the teaching of Drewes with the teaching of Bogart fails to teach or suggest a "discontinuous semi-reflective layer over a detection layer" as recited in Applicants' independent claim 45. There is no suggestion of a discontinuous semi-reflective layer over a detection layer in the devices of Drewes or Bogart as recited in independent claim 45.

For at least the reasons given above, it is respectfully submitted that the proposed combination of the teaching of Drewes with the teaching of Bogart fails to make obvious

Applicants' claimed invention as embodied in independent claims 1 and 45 (previously presented independent claim 41 has been canceled). Since claims 2-3, 7-10, 17-19, 23-28, 32 and 34 depend from independent claim 1 and recite additional claim features, the proposed combination of the teaching of Drewes with the teaching of Bogart also fails to make obvious Applicants' claimed invention as embodied in dependent claims 2-3, 7-10, 17-19, 23-28, 32 and 34 (previously presented independent claim 42 has also been canceled). Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Previously Presented Claim 6 Under 35 U.S.C. §103(a) In View of Drewes and Bogart and further in view of U.S. Patent No. 5,124,172 (Burrell)

Previously presented claim 6 was rejected under 35 U.S.C. §103(a) as being unpatentable in view of Drewes in combination with Bogart, and further in view of U.S. Patent No. 5,124,172 issued to Burrell et al. (hereinafter "Burrell"). This rejection is respectfully traversed.

Previously presented claim 6 depends from independent claim 1, and further recites that the claimed detection layer comprises a pattern of wells beneath a lower surface of the semi-reflective layer and extending a depth into the detection layer.

The proposed combination of the teaching of Drewes with the teaching of Bogart fails to make obvious Applicants' claimed invention as embodied in dependent claim 6 for the reasons given above. The teaching of Burrell fails to cure the above-noted deficiencies in the proposed combination of the teaching of Drewes with the teaching of Bogart.

The teaching of Burrell is directed to a thin film diagnostic device comprising (i) a thin sputtered layer 12 of tantalum on a substrate 11 (e.g., glass), (ii) a barrier layer 15 of tantalum oxide on sputtered layer 12, (iii) a porous anodized aluminum oxide-containing layer 14 on the barrier layer 15, and (iv) a coating 17 of reagent material on porous anodized aluminum oxide-containing layer 14. See, FIGS. 1-5. Suitable reagents include either member of a pair of molecules that selectively bind to one another to form a complex. Exemplary pairs are disclosed in column 5, lines 4-20.

Regarding the rejection of Applicants' previously presented claim 6, the September 24, 2007 Office Action states the following on page 6, lines 9-17:

Neither Drewes nor Bogart discloses a pattern of wells beneath a surface of the semi-reflective layer and extending a depth into the detection layer. Burrell, however, discloses a detection layer with wells (see figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include wells in the detection layer because Burrell discloses this feature as a known method to increase surface area for the analytes to be tested. The claim would have been obvious because the technique for improving a particular class of devices was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Applicants disagree.

The teaching of Burrell fails to disclose, teach or suggest the formation of wells in a detection layer beneath a lower surface of a semi-reflective layer. Like the teachings of Drewes and Bogart, the disclosed devices of Burrell fail to disclose, teach or suggest a polymer-containing detection layer containing wells, wherein the polymer-containing detection layer containing wells is beneath a lower surface of a semi-reflective layer as recited in claim 6. Consequently, even if the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Burrell is deemed proper (and Applicants respectfully submit that the proposed combination is improper for the reasons provided above), the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Burrell still fails to teach or suggest Applicants' claimed invention as embodied in claim 6.

For at least the reasons given above, it is respectfully submitted that the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Burrell fails to make obvious Applicants' claimed invention as embodied in dependent claim 6. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Previously Presented Claims 29, 43 and 46 Under 35 U.S.C. §103(a) In View of Drewes and Bogart and further in view of U.S. Patent Application Publication No. 2003/0207454 (Eyster)

Previously presented claims 29, 43 and 46 were rejected under 35 U.S.C. §103(a)

as being unpatentable in view of Drewes in combination with Bogart, and further in view of U.S. Patent Application Publication No. 2003/0207454 to Eyster et al. (hereinafter “Eyster”). This rejection is respectfully traversed.

As shown in the claim amendments above, the previously objected to claim language of previously presented claim 44 (and base claim 41) has been incorporated into newly presented claim 43. Consequently, the rejection of previously presented claim 43 is moot.

Regarding the rejection of dependent claims 29 and 46, Applicants respectfully submit that even if the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Eyster is deemed proper (and Applicants respectfully submit that the proposed combination is improper for the reasons provided above), the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Eyster still fails to teach or suggest Applicants’ claimed invention as embodied in claims 29 and 46. In particular, the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Eyster still fails to teach or suggest (1) a polymer-containing detection layer sandwiched between a reflective layer and a semi-reflective layer as recited in Applicants’ independent claim 1, and (2) a “discontinuous semi-reflective layer over a detection layer” as recited in Applicants’ independent claim 45.

For at least the reasons given above, it is respectfully submitted that the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Eyster fails to make obvious Applicants’ claimed invention as embodied in dependent claims 29 and 46. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Previously Presented Claim 35 Under 35 U.S.C. §103(a) In View of Drewes and Bogart and further in view of U.S. Patent No. 4,877,747 (Stewart)

Previously presented claim 35 was rejected under 35 U.S.C. §103(a) as being unpatentable in view of Drewes in combination with Bogart, and further in view of U.S. Patent No. 4,877,747 to Stewart (hereinafter “Stewart”). This rejection is respectfully traversed.

Dependent claim 35 depends from independent claim 1 and claim 34, and further recites that the sensor of claim 1 is in combination with a light source and a photo-detector.



Applicants respectfully submit that even if the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Stewart is deemed proper (and Applicants respectfully submit that the proposed combination is improper for the reasons provided above), the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Stewart still fails to teach or suggest Applicants' claimed invention as embodied in claim 46. In particular, the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Stewart still fails to teach or suggest a polymer-containing detection layer as recited in Applicants' independent claim 1.

For at least the reasons given above, it is respectfully submitted that the proposed combination of the teaching of Drewes with the teaching of Bogart and the teaching of Stewart fails to make obvious Applicants' claimed invention as embodied in dependent claim 35. Accordingly, withdrawal of this rejection is respectfully requested.

### III. New Claims 48-55:

New claims 48-55 are directed to various embodiments of Applicants' claimed invention. Support for new claims 48-55 may be found in at least the following locations of Applicants' original specification: page 7, lines 28-29 (claim 48); page 12, lines 26-28 (claim 49); page 9, lines 4-8 (claim 50); page 25, lines 7-8 (claim 51); page 16, lines 14-15 (claim 52); page 25, lines 7-8, and page 16, lines 14-15 (claim 53); page 13, lines 22-27 and page 23, lines 21-26 (claim 54); and page 24, lines 3-5 (claim 55).

For at least the reasons given above, Applicants respectfully submit that new claims 48-55 are in condition for allowance.

### IV. Conclusion:

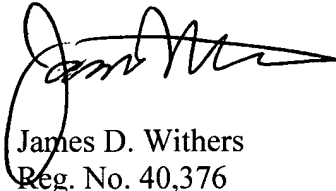
For at least the reasons given above, Applicants respectfully submit that claims 1-35, 43 and 45-55 define patentable subject matter. Accordingly, Applicants respectfully request allowance of these claims.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 503025.

Amendment and Response  
Serial No. 10/807,655

Should Examiner Akram believe that anything further is necessary to place the application in better condition for allowance, Examiner Akram is respectfully requested to contact Applicants' representative at the telephone number listed below.

Respectfully submitted,  
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